



1 P3 Rec'd PCT/PTO 14 MAR 2006 PCT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	Art Unit:
THIEL, et al.)	Examiner:
Serial No.: 10/537,507)	Washington, D.C.
Filed: December 2, 2005)	March 14, 2006
For: METHOD FOR DETERMINING)	Docket No.: THIEL=3
PREDISPOSITION TO)	Confirmation No.: 4712
MANIFESTATION OF IMMUNE...)	

INFORMATION DISCLOSURE STATEMENT [IDS]

U.S. Patent and Trademark Office
Customer Service Window
Randolph Building
401 Dulany Street
Alexandria, VA 22314

S i r :

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed:

[] A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application. See 37 CFR 1.97(b)(1) and (3).

[X] B. before the mailing date of a first office action on the merits. See 37 CFR 1.97(b).

[] C. after (A) and (B) above, but before final rejection or allowance, and Applicants have made the necessary certification (box "i" below) or paid the necessary fee (box "ii" below). See 37 CFR 1.97(c)(2).

[] i. Counsel certifies that, upon information and

belief, each item of information listed herein was either (a) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS or (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

- [] ii. Credit Card Payment Form, PTO-2038, authorizing payment for the fee set forth in 1.17(p), presently believed to be \$180, is attached.

[] D. after (A), (B) and (C) above, but before payment of the issue fee. Applicant petitions under 37 C.F.R. 1.97(d) for consideration of this IDS. A Credit Card Payment Form, PTO-2038, authorizing payment for the fee set forth in 1.17(p)(1), presently believed to be \$180 is attached. Counsel certifies that, upon information and belief, each item of information listed herein was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS or (ii) was not cited in a communication from a foreign patent office in a counterpart foreign application and was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

[] E. As a submission in accordance with the transitional procedure for limited examination after final rejection pursuant to 37 CFR §1.129(a). Pursuant to MPEP §706.07(g), page 700-66, col. 2 (August 2001), this IDS is treated as if filed with a period set forth in 37 CFR §1.97(b) and considered without the petition and petition fee required by 1.97(d).

[] F. As a submission with or after a request for continued examination under CFR §1.114, and before the mailing of a first office action on the RCE. See 37 CFR §1.97(b)(4).

2. In accordance with 37 C.F.R. 1.98, this IDS includes a

list (e.g., form PTO-1449) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document is attached, except as explained below.

[] While an IDS filed under §1.97 must contain a "list of all patents, publications or other information submitted for consideration by the Office", see §1.98(a) (1), the only requirement for the list is that it provide the information set forth in §1.98(b). There is no requirement that a form PTO-1449 be used (MPEP §609 merely says that use of this form is "encouraged"). Counsel has used a list provided to him by Applicants, and not transferred the information to a PTO-1449, to avoid the risk of any inadvertent error in transferring the information.

[X] A. Documents AA-AK are U.S. Patents or U.S. Patent Publications, and hence copies of these documents have not been provided. See 37 CFR 1.98(a)(2)(ii).

[] B. Documents _____ are deemed substantially cumulative to documents _____, and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.

[] C. Certain documents were previously cited by or submitted to the Office in the following prior application(s), which are relied upon under 35 U.S.C. 120:

[insert serial number/filing date]

Applicants identify these documents by attaching hereto copies of the form PTO-892s and PTO-1449s from the files of the prior applications or a fresh PTO-1449 listing these documents, and request that they be considered and made of record in accordance with 1.98(d). Per 37 CFR 1.98(d), copies of these documents need not be filed in this application. If copies of any of these documents cannot be found in the files of the prior applications, the Examiner is requested to so notify counsel before taking action in this case, so replacement copies can be submitted. While an IDS filed under §1.97 must contain a "list of all patents, publications or other information submitted for

consideration by the Office", see §1.98(a) (1), the only requirement for the list is that it provide the information set forth in §1.98(b). There is no requirement that a form PTO-1449 be used (MPEP §609 merely says that use of this form is "encouraged") and no prohibition on submitting a copy of a form PTO-1449 or form PTO-892 from a prior case. Indeed, the re-use of such forms is desirable as it avoids error in transferring the information, and evidences that the reference was considered in a prior application. A previously accepted PTO-1449, or an examiner-prepared PTO-892, necessarily complies with §1.98(b).

[X] 3. Document AN is not in the English language. In accordance with 1.98(a) (3), Applicants state:

[] documents _____ already contain an English language abstract, summary or claim set.

[] a publicly available abstract is attached to each of documents ____, and the source of each abstract is indicated thereon.

[X] document AN is a combination of (1) a publicly available English language abstract of a foreign language patent, and (2) a computer translation of the foreign language patent.

[] documents ____ are patents or published patent applications for which counterpart English language patents or patent applications exist, and are enclosed, as follows:

<u>Foreign Lang. Doc.#</u>	<u>English Lang. Doc.#</u>
[insert]	[insert]

[] applicants have prepared an English translation of at least the pertinent portions of documents _____, and copies are attached.

[] A concise explanation of the relevance of documents _____ is found in the attached search report from the _____ Patent Office (see reply to Comment 68 in the preamble to the final rules; 1135 OG 13 at 20).

[] A concise explanation of the relevance of documents _

_____ appears in the present specification.

[] A concise explanation of the relevance of documents _____ is set forth as follows:

[Insert concise explanation of relevance]

4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 and 68 in the preamble to the final rules; 1135 OG 13 at 20).

5. If the month of publication of a nonpatent reference is not stated, it is because it is not apparent from review of the reference. If requested to do so by the Examiner, Applicants will attempt to locate and write to the publisher.

If the publication date of a cited document is set forth only as a publication year, and that year is prior to the year of filing or, if priority is claimed, year of priority of this application, then the particular month of publication is not in issue. Likewise if that publication year is after the year of filing of this application, the month of publication is not in issue.

If the date of publication of a nonpatent reference is stated, then, except as explained below, it is the nominal date stated in the reference, or in a larger document (journal or book) from which the reference was extracted. Applicants reserve the right to challenge this date by contacting the publisher to determine the actual shipment date, or by contacting recipients to determine the receipt dates.

6. Other information being provided for the examiner's consideration follows:

[insert other information]

7. In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the

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item and Applicant reserves the right to prove that the date of publication is in fact different.

8. The Commissioner is hereby authorized and requested to charge any additional fees which may be required in connection with this paper or credit any overpayment to Deposit Account No. 02-4035.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant

By: 

Iver P. Cooper
Reg. No. 28,005

624 Ninth Street, N.W.
Washington, D.C. 20001
Telephone: (202) 628-5197
Facsimile: (202) 737-3528
IPC:lms
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SUBSTITUTE FOR FORM IPC/SB/08 INFORMATION DISCLOSURE STATEMENT LIST OF DOCUMENTS CITED BY APPLICANT			ATTY DOCKET NO: THIEL=3		SERIAL NO:	
			FIRST INVENTOR:			
			FILING DATE:			
			EXAMINER:		ART UNIT:	
U.S. PATENT DOCUMENTS (include at least patentee, patent/pub number and filing/issue/pub date)						
EXAM. INITIAL	ID	DOCUMENT NUMBER	FILING, ISSUEOR PUBLICATION DATE MM-DD-YYYY	PATENTEE OR APPLICANT	Relevant Passage(s)	T*
	AA	4,215,051	07-29-1980	SCHROEDER et al.		
	AB	4,376,110	03-08-1983	DAVID et al.		
	AC	4,704,692	11-03-1987	LADNER		
	AD	4,946,778	08-07-1990	LADNER		
	AE	5,545,806	08-13-1996	LONGBERG et al.		
	AF	5,569,825	10-29-1996	LONGBERG et al.		
	AC	5,731,181	03-24-1998	KMIEC		
	AH	5,760,012	06-02-1998	KMIEC et al.		
	AI	5,888,983	03-30-1999	KMIEC et al.		
	AJ	6,010,970	01-04-2000	MCGINTY et al.		
	AK	6,211,351	04-03-2001	KUMAR et al.		
FOREIGN PATENT DOCUMENTS (include at least document number, publication date and country)						
EXAM. INITIAL	ID	COUNTRY CODE & DOCUMENT NUMBER	PUBLICATION DATE MM-DD-YYYY	PATENTEE OR APPLICATION	Relevant Passage(s)	T*
	AL	WO 99/14226	03-25-1999	EXIQON A/S		E
	AM	WO 02/06460	01-24-2002	JENSENIUS, et al.		E
	AN	JP 2002 153299	05-28-2002	SUMIKIN BIOSCIENCE KK, et al.		T
OTHER DOCUMENTS (include AUTHOR, title, name of publication, volume, pages & date of publication) Please list in alphabetical order.						
	AO	BITTER, et al., "Expression and Secretion Vectors for Yeast", <u>METHODS IN ENZYMOLOGY</u> , vol. 153, pp. 516-544, 1987.				
	AP	CAPON, et al., "Designing CD4 immunoadhesins for AIDS therapy", <u>NATURE</u> , VOL. 337, PP. 525-531, February 9, 1989.				
	AQ	CARLSSON, et al., "Cystic fibrosis patients heterozygous for MASP-2 gene mutation have lowered MASP-2 concentration, without relation to clinical findings", <u>ABSTRACTS/MOLECULAR IMMUNOLOGY</u> , no. 80, vol. 40, pp. 208, 2003.				
EXAMINER				DATE CONSIDERED		
EXAMINER: Initial if reference considered. Draw line through citation if not in conformance <u>and</u> not considered. Include copy of this form with next communication to applicant.						

* "Relevant Passages" column is optional. Put check in "T" column if English translation of entire document included. If English language abstract included, put A in this box. If ref. in English, put "E". If requirement otherwise met, put O.

SUBSTITUTE FOR FORM IPC/SB/08 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT LIST OF DOCUMENTS CITED BY APPLICANT		ATTY DOCKET NO: THIEL=3		SERIAL NO:
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		FILING DATE:		
		EXAMINER:	ART UNIT:	
OTHER DOCUMENTS (include author, title, name of publication, volume, pages and date of publication) Please list in alphabetical order.				
	AR	COLBÉRE-GARAPIN, et al., "A New Dominant Hybrid Selective Marker for Higher Eukaryotic Cells", <u>J. MOL. BIOL.</u> , vol. 150, pp. 1-14, 1981.		
	AS	COTE, et al., "Generation of human monoclonal antibodies reactive with cellular antigens", <u>PROC. NATL. ACAD. SCI. USA</u> , vol. 80, pp. 2026-2030, April 1983.		
	AT	COLE, et al., "THE EBV-HYBRIDOMA TECHNIQUE AND ITS APPLICATION TO HUMAN LUNG CANCER", <u>MONOCLONAL ANTIBODIES AND CANCER THERAPY</u> , pp. 77-96, 1985.		
	AU	GREEN, et al., "Antigen-specific human monoclonal antibodies from mice engineered with human lg heavy and light chain YACs", <u>NATURE GENETICS</u> , vol. 7, pp. 13-21, May 1994.		
	AV	HUSE, et al., "Generation of a Large Combinatorial Library of the Immunoglobulin Repertoire in Phage Lambda", <u>SCIENCE</u> , vol. 246, pp. 1275-1281, December 8, 1989.		
	AW	INOUE, et al., "Up-promoter mutations in the <i>lpp</i> gene of <i>Escherichia coli</i> ", <u>NUCLEIC ACIDS RESEARCH</u> , vol. 13, no. 9, pp. 3101-3110, 1985.		
	AX	JANKNECHT, et al., "Rapid and efficient purification of native histidine-tagged protein expressed by recombinant vaccinia virus", <u>PROC. NATL. ACAD. SCI. USA</u> , vol. 88, pp. 8972-8976, October 1991.		
	AY	KÖHLER, et al., "Continuous cultures of fused cells secreting antibody of predefined specificity", <u>NATURE</u> , VOL. 256, PP. 495-497, August 7, 1975.		
	AZ	KÖHLER, et al., "Fusion between immunoglobulin-secreting and nonsecreting myeloma cell lines", <u>EUR. J. IMMUNOL.</u> , vol. 6, pp. 292-295, 1976.		
	BA	KÖHLER, et al., "Derivation of specific antibody-producing tissue culture and tumor lines by cell fusion", <u>EUR. J. IMMUNOL.</u> , vol. 6, pp. 511-519, 1976.		
	BB	KOZBOR, et al., "The production of monoclonal antibodies from human lymphocytes", <u>IMMUNOLOGY TODAY</u> , vol. 4, no. 3, pp. 72-79, 1983.		
	BC	LOGAN, et al., "Adenovirus tripartite leader sequence enhances translation of mRNAs late after infection", <u>PROC. NATL. ACAD. SCI. USA</u> , vol. 81, pp. 3655-3659, June 1984.		
	BD	LOWY, et al., "Isolation of Transforming DNA:Cloning the Hamster aprt Gene", <u>CELL</u> , vol. 22, pp. 817-823, December 1980.		
	BE	MORRISON, et al., "Chimeric human antibody molecules: Mouse antigen-binding domains with human constant region domains", <u>PROC. NATL. ACAD. SCI. USA</u> , vol. 81, pp. 6851-6855, November 1984.		
	BF	MULLIGAN, et al., "Selection for animal cells that express the <i>Escherichia coli</i> gene coding for xanthine-guanine phosphoribosyltransferase", <u>PROC. NATL. ACAD. SCI. USA</u> , vol. 78, no. 4, pp. 2072-2076, April 1981.		
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	BG	NEUBERGER, et al., "Recombinant antibodies possessing novel effector functions", <u>NAUTRE</u> , vol. 312, pp. 604-608, December 13, 1984.		
	BH	NIELSEN, et al., "Sequence-Selective Recognition of DNA by Strand Displacement with a Thymine-Substituted Polyamide", <u>SCIENCE</u> , vol. 254, pp. 1497-1500, December 6, 1991.		
	BI	O'HARE, et al., "Transformation of mouse fibroblasts to methotrexate resistance by a recombinant plasmid expressing a prokaryotic dihydrofolate reductase", <u>PROC. NATL. ACAD. SCI. USA</u> , vol. 78, no. 3, pp. 1527-1531, March 1981.		
	BJ	PETERSEN, et al., "GENERATION OF ANTIBODIES TOWARDS MASP-1 AND MASP-2 USING BACTERIAL EXPRESSION SYSTEMS", <u>MOLECULAR IMMUNOLOGY</u> , ABSTRACT NO. 316, vol. 35, p. 409., 1998.		
	BK	ROSSI, et al., "Substrate Specificities of Recombinant Mannan-binding Lectin-associated Serine Proteases-1 and -2", <u>THE JOURNAL OF BIOLOGICAL CHEMISTRY</u> , vol. 276, no. 44, pp. 40880-40887, November 2, 2001.		
	BL	RÜTHER, et al., "Easy identification of cDNA clones", <u>THE EMBO JOURNAL</u> , vol. 2, no. 10, pp. 1791-1794, 1983.		
	BM	SANTERRE, et al., "Expression of prokaryotic genes for hygromycin B and G418 resistance as dominant-selection markers in mouse L cells", <u>GENE</u> , vol. 30, pp. 147-156, 1984.		
	BN	SMITH, et al., "Molecular Engineering of the <i>Autographa californica</i> Nuclear Polyhedrosis Virus Genome: Deletion Mutations Within the Polyhedrin Gene", <u>JOURNAL OF VIROLOGY</u> , vol. 46, no. 2, pp. 584-593, May 1983.		
	BO	STENGAARD-PEDERSEN, et al., "Inherited Deficiency of Mannan-Binding Lectin-Associated Serine Protease 2", <u>THE NEW ENGLAND JOURNAL OF MEDICINE</u> , vol. 349, pp. 554-560, August 7, 2003.		
	BP	STOVER, et al., "Two Constituents of the Initiation Complex of the Mannan-Binding Lectin Activation Pathway of Complement Are Encoded by a Single Structural Gene", <u>THE JOURNAL OF IMMUNOLOGY</u> , vol. 162, pp. 3481-3490, 1999.		
	BQ	SZYBALSKA, et al., "GENETICS OF HUMAN CELL LINES, IV. DNA-MEDIATED HERITABLE TRANSFORMATION OF A BIOCHEMICAL TRAIT", <u>PROC. N.A.S.</u> , vol. 48, pp. 2026-2034, 1962.		
	BR	TAKEDA, et al., "Construction of chimaeric processed immunoglobulin genes containing mouse variable and human constant region sequences", <u>NATURE</u> , vol. 314, pp. 452-454, April 4, 1985.		
	BS	THOMAS, et al., "Mutation of gene for mannose-binding protein associated with chronic hepatitis B viral infection", <u>THE LANCET</u> , vol. 348, pp. 1417-1419, November 23, 1996.		
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OTHER DOCUMENTS (include author, title, name of publication, volume, pages and date of publication)				
BT	VANHEEKE, et al., "Expression of Human Asparagine Synthetase in <i>Escherichia coli</i> ", <u>THE JOURNAL OF BIOLOGICAL CHEMISTRY</u> , vol. 264, no. 10, pp. 5503-5509, April 5, 1989.			
BU	VORUP-JENSEN, et al., "District Pathways of Mannan-Binding Lectin (MBL)- and C1-Complex Autoactivation Revealed by Reconstitution of MBL with Recombinant MBL-Associated Serine Protease-2", <u>THE JOURNAL OF IMMUNOLOGY</u> , vol. 165, pp. 2093-2100, 2000.			
BV	WIGLER, et al., "Transfer of Purified Herpes Virus Thymidine Kinase Gene to Cultured Mouse Cells", <u>CELL</u> , vol. 11, pp. 223-232, May 1977.			
BW	WIGLER, et al., "Transformation of mammalian cells with an amplifiable dominant-acting gene", <u>PROC. NATL. ACAD. SCI. USA</u> , vol. 77, no. 6, pp. 3567-3570, June 1980.			
BX	ØRUM, et al., "Detection of the Factor V Leiden Mutation by Direct Allele-specific Hybridization of PCR Amplicons to Photoimmobilized Locked Nucleic Acids", <u>CLINICAL CHEMISTRY</u> , vol. 45, pp. 1898-1905, 1999.			
BY	DATABASE NO.: 2003:724939, OMURA, et al. "Genes of antibiotic-synthesizing actinomycetes and their use in analysis of gene expression profiles and gene discovery".			
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